

JUN 23 2006

K060316

510 (k) Summary

This summary is submitted by:

Fresenius Kabi AG
D-61346 Bad Homburg
 Date: 12th of January 2006

1. Contact Person

Barbara Breuer-Thal
 (Senior Manager, Head of Production Operations)
 (++49 (0) 6172 686 7785)

2. Name of the Medical Devices

Classification Name: Infusion Pump
 Usual Name: Enteral Feeding Pump
 Trade Name: Compat GO™
 Enteral Feeding Pump and Enteral Administration Sets

3. Identification of Legally Market Devices

The proposed Compat GO™ Enteral Feeding Pump and Enteral Administration Sets are substantially equivalent in intended use, function and mode of operation to the currently marked Enteral Feeding Pumps and Administration Sets:

510 (k) Number	Name	Applicant
K954735	Enteralite	Zexex Intl. Inc.
K981541	ClearStar	Frantz Medical Devel.
K040196	Kendall (Kangaroo) Control	Tyco Healthcare/Kendall

4. Device Description

The Compat GO™ Enteral Feeding Pump (a Class II device) and Enteral Administration Sets are designed to deliver formulas and Enteral hydration liquids via linear peristaltic pumping to provide nutrition for patients which are not able to ingest food orally.



The Compat GO™ Enteral Feeding System is working with the Compat GO™ Enteral Feeding Pump and the Compat GO™ Enteral Administration Sets only caused by its adapted safety and effectiveness concept.

The Compat GO™ Enteral Administration Sets are compatible with the standard pre-filled formula containers presently available on the market. The Compat GO™ Enteral Administration Sets are designed to compatible with present market Enteral access devices and accessories.

5. Device Intended Use

Compat GO™ Enteral Feeding Pump and the Compat GO™ Enteral Administration Sets are intended for Enteral feeding exclusively. The purpose of this administration system is the delivery of Enteral nutrition at controlled rates (pump assisted) to patients gastrointestinal system.

Intended for use for patient with any condition requiring Enteral feeding and Enteral hydration. The Compat GO™ Enteral Feeding Pump and the Compat GO™ Enteral Administration Sets are intended to use by adults or paediatric in hospital and home care environments, both in stationary and ambulatory ways.

6. Product Comparison

The Compat GO™ Enteral Administration system including the instruction for use (Manual) are substantially equivalent regarding safety and effectiveness to the compared feeding pumps as well as instruction for use and there administration sets (listed see point 3.).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2006

Fresenius Kabi Deutschland GmbH
C/O Mr. Stefan Preiss
Responsible Third Party Official
TUV Product Service
1775 Old Highway 8
New Brighton, Minnesota 55112

Re: K060316

Trade/Device Name: Compat GO™ Feeding Pump with Compat™ GO
Administration Sets
Regulation Number: 21 CFR 884.5725
Regulation Name: Enteral Infusion Pump
Regulatory Class: II
Product Code: LZH
Dated: June 1, 2006
Received: June 8, 2006

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060316

Device Name: Compat GO™ Feeding Pump with
Compat GO™ Administration Sets

Indications For Use:

The Compat GO™ feeding pump with the administration sets are intended exclusively for enteral feeding

The purpose of this administration system is the delivery of Enteral nutrition at controlled rates (pump assisted) to patients gastrointestinal system. Intended for use for patient with any condition requiring Enteral feeding and Enteral hydration.

The Compat GO™ Enteral Feeding Pump and the Compat GO™ Enteral Administration Sets are intended to use by adults or paediatric in hospital and home care environments, both in stationary and ambulatory ways

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
[Signature-Off]
[Signature-Off] of Anesthesiology, General Hospital,
[Signature-Off] Control, Dental Devices

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